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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
|-----------------|-------------|----------------------|---------------------|

09/462,089 05/01/00 McNAMARA

M 017227/0154

HM12/0409

EXAMINER

FOLEY & LARDNER  
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EWOLDT, G

| ART UNIT | PAPER NUMBER |
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1644

DATE MAILED:

04/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

|                              |                                      |                                     |
|------------------------------|--------------------------------------|-------------------------------------|
| <b>Office Action Summary</b> | Application No.<br><b>09/462,089</b> | Applicant(s)<br><b>Mcnamara, M.</b> |
|                              | Examiner<br><b>G. R. Ewoldt</b>      | Group Art Unit<br><b>1644</b>       |

Responsive to communication(s) filed on Jul 7, 2000

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1-36 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) \_\_\_\_\_ is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims 1-36 are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

*Fax transmittal form*

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

**DETAILED ACTION**

1. **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience.. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4315.

2. Claims 1-36 are pending.

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted:

I. Claims 1-8, drawn to a composition comprising an LHRH:diphtheria conjugate and an ionic polysaccharide.

II. Claim 9, drawn to a method of eliciting an immune response to LHRH.

III. Claims 10-11, 13-17, and 20-21, drawn to a method of inhibiting reproductive capacity in a male animal.

IV. Claims 10, 12-15, 18-19, and 22-23, drawn to a method of inhibiting reproductive capacity in a female animal.

V. Claims 24-29, drawn to a method of achieving production gains in livestock.

VI. Claims 30-34, drawn to a method of inhibiting the growth of cells.

VII. Claims 35-36, drawn to a method of downregulating libido.

4. The inventions listed do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

U.S. Patent No. 5,378,688 (1995) teaches a composition comprising an LHRH:diphtheria conjugate. U.S. Patent No. 5,5,403,586 (1995) teaches an ionic polysaccharide adjuvant for use with an LHRH conjugate (see particularly column 5, last paragraph - column 6, first paragraph). Therefore, it would have been obvious to use an ionic polysaccharide adjuvant in a

composition with an LHRH:diphtheria conjugate (see particularly column 5, line 62).

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have single general inventive concept and lack unity of invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected species, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

7. Any inquiry concerning this communication from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

G.R. Ewoldt, Ph.D.  
Patent Examiner  
Technology Center 1600  
April 5, 2001

*Patrick J. Nolan*  
Patrick J. Nolan, Ph.D.  
Primary Examiner  
Technology Center 1600